United States Patent [19]

Coplan

[11] **3,918,455**

[45] **Nov. 11, 1975**

[54] **COMBINED SURGICAL SUTURE AND NEEDLE**

[75] Inventor: **Myron J. Coplan**, Natick, Mass.

[73] Assignee: **Albany International Corporation**, Dedham, Mass.

[22] Filed: **May 31, 1974**

[21] Appl. No.: **475,102**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 464,810, April 29, 1974, abandoned.

[52] **U.S. Cl.** **128/339**; 128/335.5; 223/102

[51] **Int. Cl.**[2] **A61B 17/06**

[58] **Field of Search**..... 128/334, 334 R, 335, 335.5, 128/339, 348–350; 138/118; 223/102, 103; 112/222–224; 264/290 R; 425/461–466; 161/178, 181

[56] **References Cited**

UNITED STATES PATENTS

1,106,667	8/1914	Minahan	128/339
1,981,651	11/1934	Logan	128/339
2,072,302	3/1937	Herrmann et al	128/335.5
2,418,771	4/1947	Irwin, Jr.	161/178 X
3,212,502	10/1965	Myers	128/339
3,297,033	1/1967	Schmitt	128/335.5

FOREIGN PATENTS OR APPLICATIONS

177,070	1922	United Kingdom	128/339

Primary Examiner—Richard A. Gaudet
Assistant Examiner—Rick Optiz
Attorney, Agent, or Firm—Kenway & Jenney

[57] **ABSTRACT**

A combination suture-needle assembly wherein the suture diameter and the maximum needle diameter are preferably the same or the suture diameter may be less than the needle diameter. The needle is secured to the suture by means of a needle shank portion of smaller diameter than the maximum needle diameter, the shank being inserted into an internal or central bore provided in the suture, the needle being suitably anchored therein. The remaining length of the suture bore may be left empty, or it may be filled by pigments, tissue-reactive fluids, suture solvents, or other active or inert materials.

10 Claims, 4 Drawing Figures

doesn't say fluid capable of coming out

2nd piece doesn't have a base.

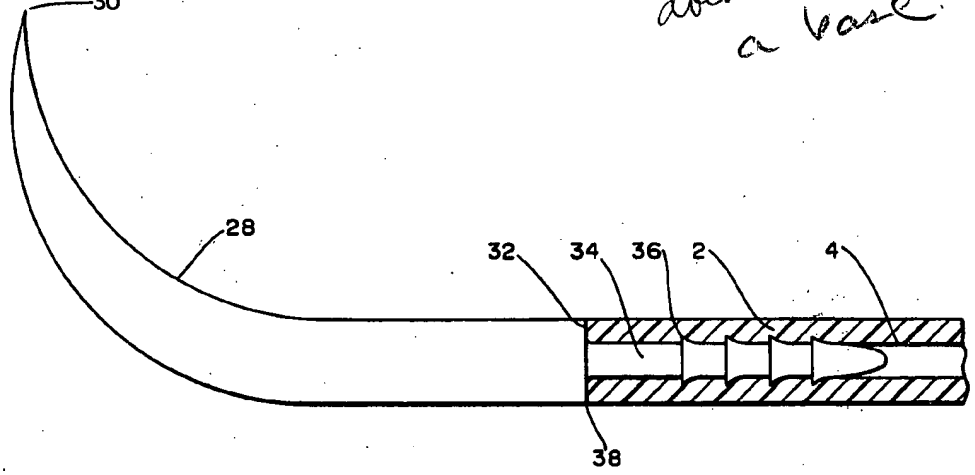


FIG. 1

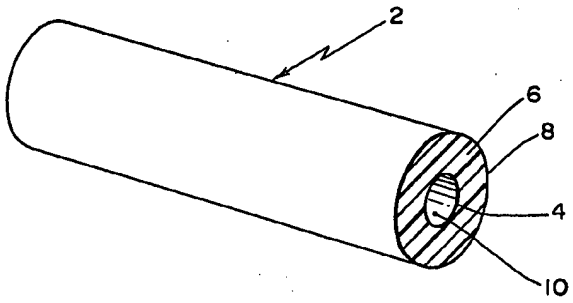


FIG. 2

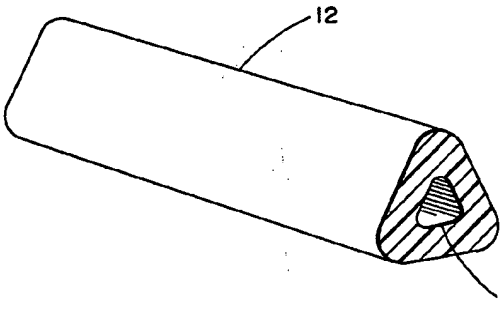
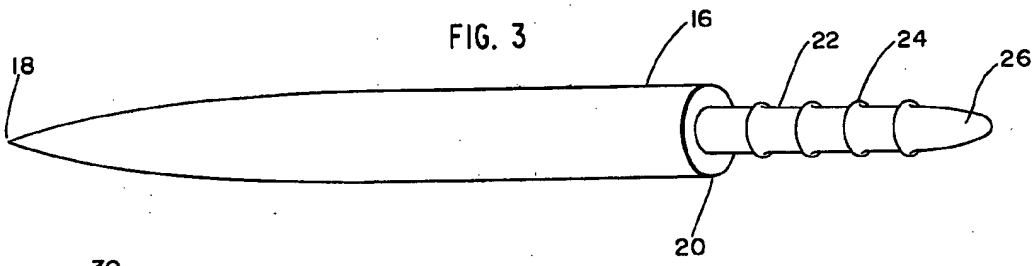


FIG. 3



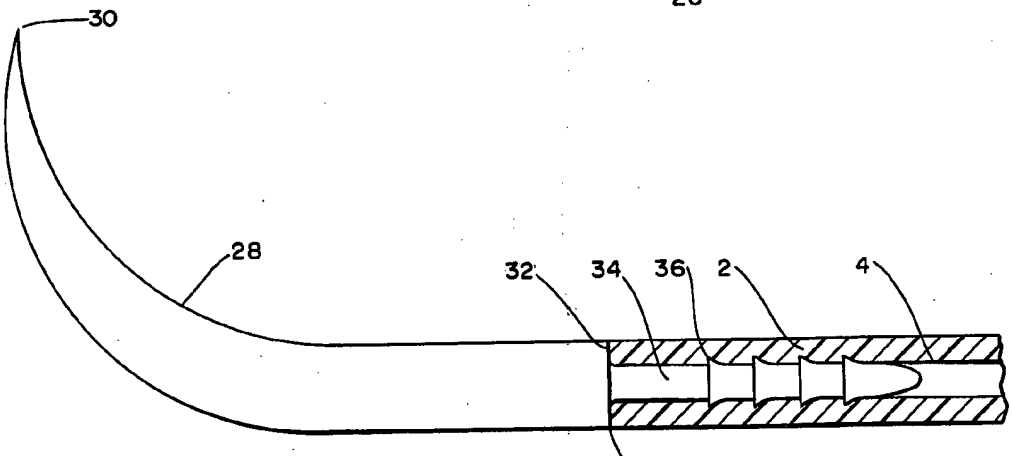


FIG. 4

COMBINED SURGICAL SUTURE AND NEEDLE

BACKGROUND OF THE INVENTION

It was at one time customary to effect suturing during surgery by means of a needle having a hole or eye drilled transversely to its axis to accept a loop of suture material threaded therethrough in the manner customarily employed in typical handsewing of fabrics. The double thickness of suture plus the thickness of the needle shank at the eye substantially exceeded the diameter of a single strand of suture; and sutured tissue, therefore, suffered considerably more trauma than would have been necessary merely to provide for penetration of a single strand of suture. This objection was partly overcome with the development of needle-suture assemblies (U.S. Pat. Nos. 1,558,037; 2,411,079; 3,394,704) wherein the needle shank at one end has a hollow bore, the axis of the bore being parallel to the axis of the needle. A suture is assembled to such a needle by having one end inserted into the needle bore and secured therein by adhesive, or by deforming the needle at the bore to clamp the suture end in place. This does, of course, reduce the size of the penetration during suturing to the maximum diameter of the needle itself.

However, it will be obvious that considerable skill is required to drill a small concentric bore in the end of a small needle. There is a feasible lower limit to the diameter of the needle that can be fabricated this way. Moreover, no matter how fine the suture one desires to use in a particular surgical procedure, the hollow-bore needle must still be significantly larger in diameter than the suture and the penetration hole therefore is larger than the suture. This contributes to unnecessary trauma and the possibility of suture slippage and tear-out. In the installation of fine prosthetic devices, for example, knitted or woven arterial grafts, the suture hole in the graft being larger than the suture itself may tend to leak blood into the adjoining tissue. Tear-out, blood leakage, and other problems with the prior art needle-suture assemblies have become increasingly important deleterious effects in the application of microsurgical techniques where the desired suture diameter is of increasingly finer diameter.

SUMMARY OF THE INVENTION

This invention concerns an improved suture, a suitably configured needle, and a combination suture and needle assembly, in which the suture comprises a hollow fiber, preferably in the form of a hollow extruded polymer monofilament. The needle is formed at its rear end with a shank portion of reduced cross-section so sized as to fit into the bore of the hollow filament and be anchored therein. A shoulder on the needle abuts smoothly against the end of the filament, which is preferably of the same outside diameter as the shoulder. If desired, the suture diameter may be made less than the outer diameter of the needle at the shank.

Among the several objectives and advantages of this invention, therefore, may be noted the provision of an improved suture and suture-needle combination intended to achieve several ends, including: reduced trauma at the site of tissue penetration, reduced hazard of suture tear-out; improved suture knotability; increased knot strength; better compatability with the procedures for installation of prostheses; enhanced visibility of the suture during surgery; controlled suture dissolution if suture sorption is desired; controlled localized application of active agents to the site of the sutured tissue. The provision of a suture itself which is a hollow monofilament, and the provision of a needle attachable easily to said monofilament and which may be reused, are also objects of the invention.

The invention accordingly comprises the elements and combinations of elements, features of construction, and arrangements of parts which will be exemplified in the structures hereinafter described, and the scope of the application of which will be indicated in the appended claims.

The suture of this invention consists of any of several appropriate materials extruded or drawn, (or otherwise made) in the form of monofilament. The essential feature of the monofilament suture is that it have a hollow bore. Its external cross-sectional shape may be round with a round bore. Alternatively, the external peripheral shape of the suture cross-section may be oval, triangular, rectangular, or other polygonal shapes. The profile of the suture bore may likewise vary from round and be similar to or dissimilar from the profile of the outer suture cross-section. The suture may be fabricated from any of the man-made, fiber-forming polymers such as the polyesters, polyamides and polyolefins, which are acceptable for surgical suture applications; for example, nylon, polyethylene, polypropylene, polyethylene terephthalate, polylactide/glycolide copolymer, and polycarbonate. Regenerated collagen, although a naturally occuring polymer rather than man-made, may also be used, since fibers are produced therefrom in apparatus similar to man-made fiber spinning equipment. The art of hollow fiber extrusion is well-known, being variously described in U.S. Pat. Nos. 3,630,824; 3,686,377; 3,600,491; 3,313,000; 3,174,364; 3,095,258. In the instant invention the particular polymer used or extrusion technique is of no significance except insofar as it is necessary that the material be suitable from the medical standpoint and the shape and dimensions of the filament and its hollow bore be appropriately matched to a selected needle shape and dimensions, as will become apparent during further discussions hereunder.

The needle of this invention is of a novel configuration and may be described as comprising a point end integrally joined to a shank end. The point end is considered to begin at the sharp tip of the whole needle and generally extends in length from a fraction of an inch (such as 3/16 inch) to perhaps two or more inches. Diameters of the point end, that is, the non-shank portion, may range from 0.002 inch upward to the diameter which is consistent with the needle length, bearing in mind the need of stiffness (but with some degree of flexibility) of the particular needle. Corresponding sutures would have an external diameter ranging from 0.002 inches up to the diameter of the shoulder where the shank joins the body of the needle.

The point end may be straight and of simple cylindrical profile from the sharp tip to a plane of juncture with the shank end. The point end may, alternatively, be of curved or hooked shape in elevational view. The cross-sectional profile may vary along the length from cylindrical, being at various positions triangular, spatulate, ovoid, or the like. In any event, the cross-sectional area generally grows from the tip with successive cross-sectional planes smoothly merging without steps or abrupt changes in area or shape until the plane of junction with the shank end. Here the point end abruptly termi-

nates and the needle diameter steps down to a smaller cross-sectional area forming the shank end. At the plane of juncture with the shank end, the abrupt step-down creates a shoulder lying in a plane transverse to the axis of the shank end. The shank surface may be roughened as by corrugations, knurling, serrations, burring, threading, or the like. In general, the cross-sectional profile of the shank may be round when the cross-sectional profile of the shoulder is round. The shank end profile may be of similar shape but smaller in cross-sectional area than the shoulder of the point end when the latter deviates from round, as for example triangular, ovoid, or the like. The shank end may also be dissimilar in cross-sectional profile from the profile of the shoulder of the point end or any other portion of the point end; for example, a flattened shank may connect to a round point end.

The combination needle and suture comprises an assembly wherein the shank end of the stepped needle is fully inserted into the filament's hollow bore with said shoulder resting against the smooth cut end of the suture; the diameter and shape of said shoulder and the outside diameter of the suture being essentially the same. The corrugations of the shank provide secure anchorage of the suture to the needle. It is an essential feature of the best embodiment of this invention that the cross-sectional profile of the end of the hollow suture conform to the profile of the shoulder of the point end, thereby forming a smooth stepless transition between needle and suture, although if desired but not as good, the outer diameter of the suture may be less than the needle diameter at the shank juncture. This shape and area conformance of the suture may be controlled at least in part by the combined effect of specific shape and cross-sectional dimensions of the shank, the suture bore, and the over-all dimensions of the suture cross-section. In any event, the cross-section of the needle at its junction with the suture must not be significantly larger than the suture. During surgery, therefore, the tissue penetration hole is not unnecessarily enlarged. As a result, the tissue suffers the least possible trauma; danger of tissue tearing and suture pull-out is minimized; leakage of blood through over-enlarged holes in tissue or prosthesis is eliminated.

The suture material may be of the so-called permanant type or of the absorbable type. In the latter instance, it may be of some advantage at the time of installation of the suture during surgery to fill the capillary core of the filament with a suitable degrading agent so that the suture material will be exposed to a more effectively controlled rate of dissolution than that occasioned by body fluids.

The suture material may be so extruded and drawn, as to have been converted to a state known as microporous "hard elastic" (Quynn, R., and Brody, H. — J. Macromol. Sci. — Phys BS(4), Dec. 1971). In this state, the polymer comprising the wall would permit fluid contained in the hollow bore to gradually diffuse through the wall of the suture into the surrounding tissue. This provides an opportunity to perfuse small amounts of active materials (disinfectants, healing aids, etc.) at the site of the sutured tissue.

In any event, the hollow bore of the suture can be filled by any simple means, such as capillary rise, or injection under pressure, with highly colored or pigmented inert fluid so as to render the suture as a whole more visible than the transparent polymer comprising the wall thereof. Likewise, the bore may be filled with a solution or dispersion of radio-opaque material to render the suture visible, after closure of the tissue, by X-radiography.

In the accompanying drawings, in which several embodiments of the invention are shown:

FIG. 1 is an enlarged view of a portion of a first embodiment of this invention comprising a hollow monofilament suture having a cylindrical bore.

FIG. 2 is an enlarged illustration of a portion of a second embodiment of the invention comprising a hollow monofilament having a non-round bore.

FIG. 3 is an enlarged elevational view of one embodiment of a needle of this invention, being a straight needle showing the point end and reduced-diameter shank end.

FIG. 4 is an enlarged view, partly in section, of another embodiment of a needle of this invention combined with a hollow filament suture in an assembly of this invention.

Similar reference characters indicate corresponding parts throughout the several views of the drawings.

Dimensions of certain of the parts as shown in the drawings may have been modified and/or exaggerated for the purposes of clarity of illustration.

Referring to the drawings, FIG. 1 shows a portion of a first embodiment of a suture of this invention, identified generally by numeral 2. The suture may be made of any of the materials listed above. As shown, it is circular in cross-section and is provided with a hollow bore 4, thus forming the wall 6 of the suture which has the external surface 8 of predetermined diameter. The bore has the interior surface 10 and has a predetermined diameter.

Referring to FIG. 2, a portion 12 of a second embodiment 12 of the suture of this invention is shown. In this case, the cross-sectional shape of the suture is triangular with rounded corners. An interior bore 14 is provided, and it likewise is triangular, and preferably its walls parallel to the outer walls of the suture.

As indicated above, sutures having other external shapes may be used, and the shape of the internal bores may or may not necessarily be the same as the shape of the outer surfaces of the suture. However, for ease of use and ease of manufacture, it is preferred that the shape of the interior bore be the same as the external shape of the suture.

Referring to FIG. 3, one embodiment 16 of a needle of this invention is shown which, in this embodiment, comprises a point end portion which extends from the sharpened left-hand extremity 18 (as viewed) to a shoulder 20 at the right-hand extremity of the portion. From the sharpened tip 18 to the shoulder 20, the needle increases in cross-section.

A shank end portion 22 extends from the shoulder 20, and is provided, as an example, with the serrations 24, the function of which is to securely hold the end of a suture onto the shank end when the shank is inserted into the bore of the suture. The number of serrations is not critical, and expediency will dictate the number used. Instead of serrations, a screw thread may be formed on the shank end 22 so that the needle may be screwed into the bore of the suture. Other fastening means may be provided such as by just roughening the shank end, knurling it, or providing it with barbs, etc. Where the shank diameter is extremely small, it may be smooth and sufficient strength will be provided by the cement used to hold the suture and needle together.

It will be noted that the cross-section of the right-hand end of the needle end portion is circular, and thus the circular suture shown in FIG. 1 will be used with the FIG. 3 needle. The external diameter of the suture of FIG. 1 and the diameter of the shoulder 20 are to be the same, so that when the suture of FIG. 1 is mounted on the shank end 22 (by forcibly inserting the latter into the bore 4), there will be a smooth continuous external surface provided at the junction of suture and needle without roughness, and thus tissue trauma will be avoided.

If desired, the end 26 of the shank may be pointed or rounded to permit facile insertion of the shank end into the bore of the suture.

Referring to FIG. 4, there is shown in greatly enlarged view a portion of a suture attached to a needle, the needle 28 in this instance, being a curved type. Needle 28 has the needle end portion termination at one end by the point 30, and terminating at the other end by a shoulder 32 like the shoulder 20. The shank end portion 34 is provided at the shoulder, the shank end being provided with the serrations 36. If shoulder 32 is circular, the circular suture of FIG. 1 is used as described above. That is, the hollow monofilament 2 such as that shown in FIG. 1 is mounted upon the shank end 34 by inserting the latter in the bore 4 of the suture. It will thus be observed that the serrations 36 become embedded in the inner wall of the bore and thus securely fasten the suture to the shank end.

As indicated above, the diameters of the point end of the needle at the shoulder 32 and the diameter of the suture 2 are to be the same at the juncture 38 of the end of the suture and the shoulder, so that there is a smooth transition from one to the other.

Where a needle is to be used which at least at the shoulder is, for example, of polygonal shape such as triangular, then the suture of FIG. 2 is to be used, with the dimensions of the sides of the shoulder triangle (and curved apices if any) being matched exactly by the dimensions of the sides of the triangular suture (and the latter's curved apices if any). Similar considerations are to govern the fitting of other polygon-shaped needle shoulders to matching polygon-shaped hollow monofilament sutures.

The assembly of the shank into the bore of the filament may be accompanied by the application of heat to shrink the filament tightly onto the shank and encourage thorough interpenetration with the rugosities on its surface. As another option, suitable adhesive may be applied at the site of the shank-filament juncture to enhance further the bonding efficiency.

It is also possible to provide a needle whose shank cross-sectional area slightly exceeds the hollow core cross-sectional area. Thus, upon forced insertion of the shank into the hollow filament, the wall thereof will be slightly distended and the outside diameter of the filament along the zone encasing the shank may exceed that of both the needle at its shoulder and the remainder of the suture beyond the entry point of the shank. This excess diameter may be eliminated by rolling the filament between heated platens until the polymer flows slightly under the pressure. Or, the suture-needle assembly may be passed between grooved rolls, the grooves thereof being exactly sized to the diameter of the needle shoulder.

Table I below sets forth examples of needles and sutures that have been successfully made:

Table I

Examples of Tested Sutures and Needles of this Invention

Polymer	(A) SUTURES O.D. (mils)	I.D. (mils)	Tenacity (gpd)	(B) NEEDLES Shape	Major Diam. (mils)	Shank Diam. (mils)
Polyhexamethylene Adipamide	2.2	0.6	—	—	—	—
Polycaprolactam	19.7	12.5	—	Curved	20.0	13.0
Polyethylene Terephthalate	8.3	4.0	4.3	Straight	8.5	4.0
Polypropylene	8.4	3.4	5.9	Straight	8.5	4.0
Polyoxymethylene	4.8	4.1	4.8	—	—	—
Polyethylene Terephthalate	10.2	3.1	2.9	Straight	10.3	3.6

In Table II are shown knot efficiencies corresponding to the sutures of Table I(A)

Table II

Polymer	O.D. (mils)	I.D. (mils)	Knot Efficiency (%)
Polyhexamethylene Adipamide	2.2	0.6	—
Polycaprolactam	19.7	12.5	—
Polyethylene Terephthalate	8.3	4.0	83
Polypropylene	8.4	3.4	71
Polyoxymethylene	4.8	4.1	81
Polyethylene Terephthalate	10.2	3.1	100

Knot efficiency was determined as follows: A simple overhand knot was formed in a length of the particular suture. The section of the suture having the knot was then pulled to rupture (which occurred at the knot) in standard test equipment and under standard conditions. The knot efficiency was then calculated by taking the tensile strength (rupture force) of the knotted suture of this invention as a percent of the tensile strength (rupture force) of an unknotted length of that suture under the same standard conditions. Tenacity is a technical word used by the fiber industry and means the specific force required to rupture a fiber.

In Table I, tenacity is a word used in the fiber industry and the (gpd) indicates grams per denier required to rupture the suture. The needles were made of stainless steel and the shank was held in the suture bore by adhesive suitable for the material used.

It will be noted that no needle is provided for the suture having an O.D. of 2.2 mils. However, the suture itself has been made, and when used with a conventional needle, works satisfactorily. Since it is hollow (as well as the other sutures of this invention), it may if desired, be filled with any of the materials mentioned

above, such as a degradant material, or antiseptics, or dyed opaque to Xrays. Because of its hollow nature, the suture has the enhanced knot-retaining characteristic mentioned below.

Other advantages accruing from the hollow suture are improved knotability and increased knot strength efficiency. In general, it is desired to be able to slide a length of suture smoothly and easily through various loopshapes until a knot is formed and pulled tight. Thereafter, it is desired that the formed knot retain its tightened configuration against the various stresses of further suturing or subsequently arising from post-surgical activity. In the instance of the hollow-bore filament, the ease of forming a knot and sliding of filaments through loops is quite high, but once a knot has been formed and pulled tight, the compressibility of the hollow filament permits filament profile shape changes, compacting the filament diameter locally under the tension of knotting. This local filament distortion tends to lock in the knot shape more tightly, and, in fact, makes for a more compact knot. Likewise, the distortability of the wall of the hollow filament contributes to superior distribution of stresses at the knot and improved translation of straight tensile strength into knot strength.

The sutures of this invention enjoy all the known advantages that monofilament sutures have demonstrated over the braided multifilament silk or cotten sutures. Obviously, these materials being of natural origin and used in their original fine-fiber state are not monofilaments. Rather, sutures comprised of silk or cotton have customarily been produced in the form of twisted and plied yarns, or braided yarns. Structures such as these tend to encourage infection because of the interstitial crevices capable of trapping and retaining tissue, plasma, and the like, whereas no such difficulty arises from smooth-surfaced monofilaments. Likewise, knot slide-down is found easier in the monofilament sutures than in braided strands because of the surface friction of the latter.

As indicated, while the bore of the suture and the shank end of the needle may each conveniently be circular in cross-section, these may also each be of some other cross-sectional profile. For example, in the preparation of hollow filaments from segmented arc type spinnerets the hole shape may approximate a rounded-corner triangle, square, or some other polygon. A shank of similar cross-section may be fabricated to essentially match the non-round hole shape. Ridges, corrugations, or screwlike threads on the shank of the needle are intended for biting into the internal surface of the filament wall and these may be exaggerated to secure even better anchorage at the thickened zones associated with non-round contours. The solid cross-sectional area of the monofilament is to comprise from 20% to 90% of the total cross-sectional area of the suture.

The diameters of the needles at the needle shank juncture may lie within the range of 2 to 30 mils with said shank portions lying within the range of 1 mil to 20 mils, and the outside diameters of the sutures may lie within the range of 2 – 30 mils, with the bore diameters ranging from 1 to 20 mils.

As to the smaller diameter needles, the reduced-diameter shank portion may be formed, if desired, by electrochemical machining or forming processes already known in the art.

It will be understood that the needle and suture combination may be prepared, assembled, and packaged as a combination. Alternatively, the needle and suture may be assembled by operating-room personnel immediately prior to or during the surgical use thereof. This provides a further desirable advantage of this invention — that broken or blunted needles may be replaced at the head end of a particular suture filament during the course of the suturing process if this appears to be required.

In view of the above it will be seen that the several objects of the invention are achieved and other advantageous results attained.

It is to be understood that the invention is not limited in its application to the details of construction and arrangement of parts illustrated in the accompanying drawings, since the invention is capable of other embodiments of being practiced or carried out in various ways. Also, it is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation.

As many changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings, shall be interpreted as illustrative and not in a limiting sense, and it is also intended that the appended claims shall cover all such equivalent variations as come within the true spirit and scope of the invention.

Having described the invention, what is claimed is:

1. In combination, a suture and needle joined together, the suture comprising a length of monofilament having an internal bore and having an external predetermined peripheral shape of predetermined first dimensions; the needle comprising a needle end portion and a shank end portion, the needle end portion extending from a point at one end thereof to a shoulder at the other end thereof, the periphery of the needle at the shoulder having the same shape as said first peripheral shape and having corresponding cross-sectional dimensions no less than said first dimensions; the shank end portion extending from the shouldered end of the needle end portion and being of predetermined dimensions and shape smaller than the external dimensions of the suture, said shank end portion being inserted into and held in said bore with the end of the suture abutting said shoulder in close engagement therewith.

2. The combination of claim **1**, in which at the juncture of the needle and the suture at the said shoulder, the transition lengthwise from the needle material to the suture material is smooth.

3. The combination of claim **1** in which the transverse cross-section of each of the suture and bore is circular, the outside diameter of the suture ranging from approximately 0.002 inches to approximately 0.03 inches, and the diameter of the bore ranging from approximately 0.001 inches to approximately 0.020 inches; and the diameter of the needle at the juncture of the shank portion and the needle end portion ranging from approximately 0.002 inches to approximately 0.030 inches.

4. The combination of claim **1** in which the needle has a length ranging from 3/16 inch upwardly to 2 inches.

5. The combination of claim **1**, in which the suture has a polygonal outer surface.

6. The combination of claim **1**, in which the suture material is a man-made fiber-forming polymer.

7. The combination of claim 1, in which the suture material is a fiber-forming polymer selected from the group consisting of the polyesters, polyamides, and

copolymer, and polycarbonate.

9. The combination of claim 1, in which the shank end of said needle is provided with means to hold the